uct. A 30 MHz, focused transducer is incorporated in the body of the rotating cutter. Because of the relatively large aperture of the transducer (0.040"), resolution and penetration are superior to stand-alone IVUS catheters. In order to provide maximum rotational stability for imaging, a fixed-wire catheter configuration has been selected for initial production. The GTO™ shaft design has been adopted for torque control.

11 GDCA catheters, 8 with standard (3.25 mm) balloons and 3 with graft (4.5 mm) balloons, were tested in 4 normal farm pigs and 3 pigs with injury models of coronary stenosis. All catheters were able to be selectively directed into the target vessel/lesion with good torque control. High resolution of the images allowed the clear demonstration of intima, venous structures, pericardium and myocardium. With balloon inflations the adequacy of engagement of the arterial wall by the cutter was directly visualized.

In vitro testing using fresh porcine aorta compared the cutting ability of the combined device to the standard GTO. The weights of single cuts were not significantly different at 10 psi (5.8 mg vs 6.2 mg), and 30 psi (7.9 mg vs 8.1 mg). To fill the nose cone of the GDCA 6.4 cuts were required compared to 5.8 for the GTO (p = ns). The weights of tissue from the filled nose cones were not significantly different (26.5 gm vs 20.5 gm).

Summary: High resolution ultrasound imaging has been combined with a directional atherectomy catheter in a configuration suitable for clinical trials.

761 Clinical Studies of Coronary Artery Angioplasty

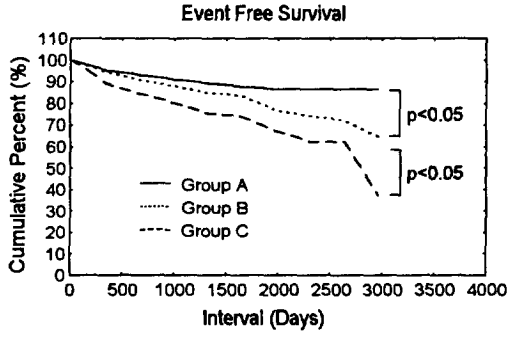
Tuesday, March 21, 1995, 4:00 p.m.–5:30 p.m.
Ernest N. Morial Convention Center, Room 90

4:00

761-1 Correlation of Residual Stenosis Immediately After Coronary Angioplasty with Long Term Prognosis

Shunichi Miyazaki, Koichi Nakao, Akira Itoh, Satoshi Daikoku, Yusuke Yamamoto, Hiroshi Nonogi. *National Cardiovascular Center, Osaka, Japan*

Although low residual stenosis decreases occurrence of restenosis within 3–6 months, its influence on long term prognosis remains unknown. Therefore, 595 consecutive patients with successful elective balloon coronary angioplasty (PTCA) for de novo lesions were divided into 3 groups according to the percent diameter stenosis (DS) immediately after PTCA. They were group A = DS < 15% (n = 129), group B = 15% ≤ DS ≤ 35% (n = 356), and group C = 35% < DS < 50% (n = 105). Background of each group was not statistically different in terms of age, history of myocardial infarction (MI), ejection fraction, distribution of both number of diseased vessels and target vessels and risk factors such as hypertension, hyperlipidemia and diabetes mellitus. End points of observation were 1) cardiac death (sudden death, fatal acute MI and death due to heart failure), 2) non cardiac death, and 3) cardiac event (acute MI and coronary bypass surgery). Kaplan-Meier survival analysis showed significant difference among 3 groups. Moreover, event free survival curve seems to be dependent on the residual stenosis (Figure). Multivariate analysis using Cox proportional hazard regression model identified that age, ejection fraction and residual stenosis were the independent determinants for the long term prognosis.



Conclusion: Lower residual stenosis immediately after PTCA is beneficial not only for preventing early occurrence of restenosis but also for long term prognosis.

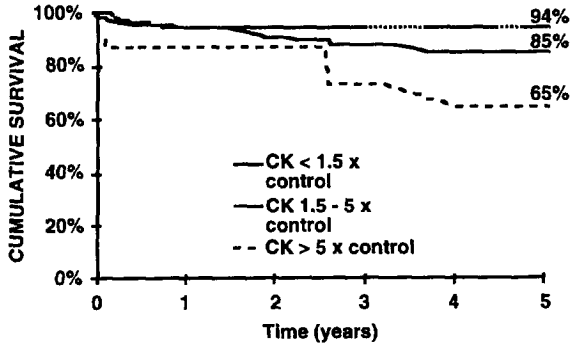
4:15

761-2 Prognostic Value of Creatinine Kinase Elevation Following Elective Coronary Artery Interventions

Jason T. Tauke, Thomas Q. Kong, Sheridan N. Meyers, Gopal Srinivasan, Paulette R. Niemyski, Michele A. Parker, Charles J. Davidson. *Northwestern University Medical School, Chicago IL*

Long term prognosis was evaluated in 250 consecutive pts (age 62 ± 12 years, 70% male) who developed creatinine kinase (CK) elevation following elective coronary artery interventions (balloon PTCA, directional coronary atherectomy, TEC atherectomy, and excimer laser). CK levels were obtained in all pts every 6 hours for at least 24 hours after PTCA. Median follow up was 2.5 yrs. (0.8, 43) and was obtained in 211 (85%) pts.

Results: Cardiac death occurred in 26/211 (12%) pts at 1.2 ± 1.3 years after intervention (range 0.0–4.0 years). Univariate predictors of cardiac death include peak total CK ($p < 0.0008$), age ($p < 0.01$), prior coronary artery bypass surgery ($p < 0.04$), and Q wave myocardial infarction after PTCA ($p < 0.04$). There were no differences in cardiac death rates between devices. Multivariate predictors of cardiac death were peak total CK ($p < 0.0004$) and age ($p < 0.01$). Actuarial survival was related to the degree of CK elevation as shown below:



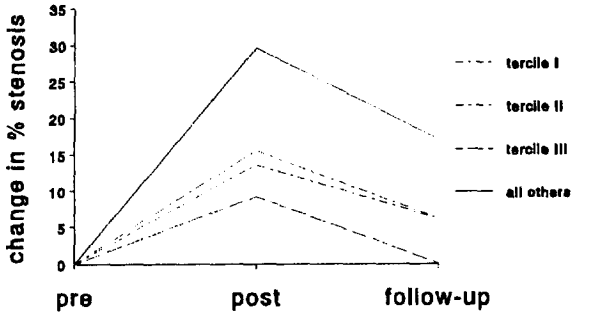
Conclusions: CK elevation following elective PTCA is associated with an increased risk of cardiac death at long term follow up. The degree of CK elevation and age are independent predictors of late cardiac death.

4:30

761-3 Interventional Treatment of "Insignificant" Stenoses

Kenneth G. Lehmann, David P. Foley, Rein Melkert, Patrick W. Serruys. *Thoraxcenter, Rotterdam, Netherlands; University of Washington, Seattle, WA*

Traditionally, coronary lesions with <50% diameter stenosis are considered clinically insignificant. However, these lesions often initiate acute coronary thrombosis and infarction. Moreover, they are regularly if unintentional treated when interventionalists "clean up" a diffusely diseased vessel. To investigate this issue, quantitative analysis was applied to 3,799 discrete stenosis undergoing PTCA at multiple centers. Of these, 668 (17.9%) possessed a pre-procedural diameter stenosis of <50%. These lesions were further subgrouped by terciles (≤42%, 42–47%, >47%). Compared to diameter stenoses ≥50%, these lesions were significantly more eccentric ($p < 0.0001$), shorter ($p < 0.0001$), located in the LAD ($p = 0.0003$), and associated with multilesion PTCA ($p < 0.0001$). The therapeutic approach chosen involved larger balloons (balloon/artery ratio = 1.21 vs 1.10, $p < 0.0001$) but was accompanied by shorter inflation times (264 sec vs 320 sec, $p < 0.0001$). Although the acute improvement in MLD was less (0.39 vs 0.81 mm,



TUESDAY PM

$p < 0.0001$), loss of this improvement during follow-up was relatively high (loss index = 0.86 vs 0.44, $p = 0.013$), so that the net improvement at 6 months was one third that seen with the more severe stenoses (net gain = 0.17 vs 0.48 mm, $p < 0.0001$). Moreover, a substantial proportion of stenoses were more severely narrowed 6 months after the procedure than before (29.0% vs 15.4%, $p < 0.0001$).

Conclusion. Treatment of "insignificant" stenoses is relatively frequent. Despite more aggressive balloon sizing, short and intermediate term results are disappointing.

4:45

761-4 Angioplasty in Borderline Lesions of <50% Diameter Stenosis for Unstable or Post-Infarction Angina is not a Benign Procedure

Waqar H. Ahmed, Clyde R. Meckel, Robert N. Piana, Deborah Manuelian, Burt Adelman, John A. Bittl, Hirulog Angioplasty Study Investigators. *Brigham and Women's Hospital, Boston, MA*

Absence of a significant lesion of ≥50% diameter stenosis is considered a contraindication to PTCA. In unstable or post-infarction angina, however, PTCA of borderline lesions of <50% diameter stenosis may be warranted because of the dynamic nature of cyclic flow reduction due to intermittent platelet plugging. To define the clinical and angiographic outcome of PTCA of borderline lesions, we analyzed the results in patients undergoing PTCA for unstable or post-infarction angina in the Hirulog™ Angioplasty Study. Of 3051 patients with validated clinical data and films analyzed in the Core Angiographic Laboratory, 227 (7.4%) had PTCA performed exclusively for lesions <50% diameter stenosis. In this group of patients, the mean pre-treatment stenosis was 40 ± 9% (range, 0–49.9%), and the mean post-angioplasty stenosis was 26 ± 15% (range, −20–100%). In comparison with patients with more severe lesions, patients with borderline lesions of <50% stenosis had similar age, sex distribution, incidence of rest angina, and PTCA complication rates:

	<50% stenosis	≥50% stenosis	P value
n	227	2824	
Procedural success (%)	93.0	85.1	0.001
Abrupt vessel closure (%)	4.9	5.8	0.55
Death (%)	0.0	0.5	0.31
Myocardial infarction (%)	2.6	3.2	0.67
Emergency bypass (%)	2.2	2.2	0.99
Clinical restenosis (%)	11.3	13.1	0.60

Clinical restenosis results at 6 months (death, MI, or revascularization) were available for 1387 (45%) patients.

In summary, these results suggest that PTCA of lesions <50% diameter stenosis is not a benign procedure and carries similar risks as PTCA for more severe lesions. This warrants a cautious approach to intervention in such lesions and further study into their natural history.

5:00

761-5 Evolution of Angiographic Thrombus Formation and Dissection Following PTCA in Unstable Angina

John A. Ambrose, Orlandino D. Almeida, Denise Ratner, Samin K. Sharma, Jonathan D. Marmur, Sabino Torre, Douglas Israel, TAUSA trial. *Mount Sinai Hospital, New York, NY*

Acute closure and adverse in hospital clinical events are increased following PTCA in unstable angina. Both thrombus (T) and dissection (D) post PTCA are associated with increased adverse events. However, the time course of development of T or D post PTCA has not been studied. In the TAUSA trial, unstable angina patients were blindly randomized to intracoronary Urokinase or placebo administered during and immediately following PTCA of the culprit lesion. Angiograms were read blindly by a core lab and characterized at 1 & 15 minutes following PTCA for T or D. D was divided into minor (linear extraluminal cap without luminal compromise) and major (spiral D or D causing >50% diameter reduction). T was defined as one or more filling defects at the PTCA site.

	Thrombus		Major Dissection	
	1 min.	15 min.	1 min.	15 min.
All pts (n = 459)	4.4%	14.8%*	6.7%	9.2%
Urokinase (n = 226)	4.1%	11.9%*	5.9%	10.1%†
Placebo (n = 233)	4.8%	17.5%*	7.4%	8.3%

* $p < 0.005$ 15 min. vs. 1 min.; † $p = 0.10$ 15 min. vs. 1 min.; all other NS

For all pts and for Urokinase and Placebo, angiographic T increased at 15 vs. 1 min post PTCA. There was a trend to an increase in major D with Urokinase at 15 min but not in the placebo group. Any D (major or minor) was noted with placebo in 24% and 29% at 1 and 15 min. respectively and in 27% and 32% with Urokinase, p = NS. Thus, T formation develops gradually following PTCA and is time dependent probably related to activation of coagulation. D is usually present immediately after PTCA secondary to the mechanical trauma of balloon dilatation. Urokinase given immediately after PTCA may increase the evolution to major D.

5:15

761-6 PTCA in the Elderly: Epidemiology, Clinical Risk Factors and Their Relationship to Outcomes

David Wennberg, David J. Malenka, John Robb, Mirle A. Kellett Jr., Samuel Shubrooks, William A. Bradley, Michael J. Hearne, Peter VerLee, Hebe Quinton, Gerald T. O'Connor, Northern New England Cardiovascular Disease Study Group. *Dartmouth-Hitchcock Medical Center, Lebanon, NH*

We report on 521 patients ≥80 years old (AGED) from a regional, population-based study of 12,902 hospitalizations for PTCA between 10/89–12/93. Over this time period, the proportion of AGED doubled to 4.4%. Compared to younger patients, AGED were more likely female, had fewer cardiac risk factors and more severe coronary disease. They had more urgent procedures and more complex lesion type. AGED clinical success was 91.36%. Their risk of nonfatal MI or CABG was similar to younger patients.

Age	≤59 (n = 5591)	60–69 (n = 3968)	70–79 (n = 2822)	≥80 (n = 521)
Female (%)	22.4	33.2	45.5	56.5†
Smokers (%)	47.6	27.2	16.0	10.4†
Multi-vessel disease (%)	31.9	39.8	45.1	57.9†
Lesion type B/C (%)	50.7	53.0	53.4	59.6†
Priority urgent (%)	57.5	58.6	61.9	72.2†
Nonfatal MI/CABG (%)	4.59	5.09	4.53	5.19
Death (%)	0.27	0.76	1.91	3.45†
Clinical Success* (%)	95.14	94.15	93.56	91.36†
Multivariate OR Death (%)	1	2.46	6.33	9.09

(† $p < 0.01$) (* no MI/CABG/Death and ≥1 lesions dilated)

Their risk of death was substantially increased and remained increased in a multivariate model controlling for risk factors. *We conclude* that clinical success following PTCA for the AGED is good. However, they have an increased risk of fatal outcomes following PTCA. This information may be helpful in counseling the rapidly growing number of AGED patients contemplating PTCA.

762 Pediatric Cardiology and Surgery: Applied Research

Tuesday, March 21, 1995, 4:00 p.m.–5:30 p.m.
Ernest N. Morial Convention Center, Room 103

4:00

762-1 A Study in Ventricular-Ventricular Interaction: Single Right Ventricles Compared with Systemic Right Ventricles in a Dual Chambered Circulation

Mark A. Fogel, Paul M. Weinberg, Kenneth E. Fellows, Eric A. Hoffman. *The Children's Hospital of Philadelphia, Philadelphia, PA 19104*

Ventricular-ventricular interaction (VV) is known to occur in the normal human heart. Because a subgroup of single right ventricle pts who have undergone the Fontan procedure (F) present in ventricular failure, we compared systemic right ventricles *with and without* a mechanically coupled left ventricle to determine the biomechanical effects of ventricular interdependence. A magnetic resonance tagging technique which lays stripes down on the myocardium called spatial modulation of magnetization was employed to examine 18 pts with systemic right ventricles: 7 F and 11 with transposition of the great arteries who have undergone an atrial inversion operation (AIO). The systolic motion of the intersection points were tracked to determine regional twist, radial motion and finite strain analysis was applied to the grid lines to derive principle E1 strains at the atioventricular and apical short axis levels and in 4 anatomic wall regions.

Strain: Strain was greatest (−0.2 ± 0.02 at the posterior wall at the atrioventricular valve) and heterogeneity of strain least (coefficient of variation 0.46 ± 0.03 at the inferior wall at the atrioventricular valve) in pts with AIO (6/8 regions). Marked differences were noted in strain distribution within a given region, from endocardium to epicardium (strain distribution across the thickness of the myocardium), and from atrioventricular valve to apex (strain distribution along the ventricular long axis) between pt subtypes and the normal left ventricle.